IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Chandler R. DAWSON *et al.*	
	Art Unit: To Be Assigned
Appl. No.: To Be Assigned	Examiner: To Be Assigned
Filed: January 24, 2001	Atty. Docket: 03654.0250.CNUS02
For: Topical Treatment or Prevention of Ocular Infections	

Preliminary Amendment

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination on the merits, please amend the above-referenced application as requested herein. It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 08-3038 referencing docket number 03654.0250.CNUS02.

Amendments

In the Specification:

On page 1, lines 3-5, please delete "This application is a continuation-in-part of prior U.S. patent application serial no. 09/282,165, filed March 31, 1999, the entire contents of

which are incorporated herein by reference." and insert therefore --This application is a continuation of application serial no. 09/346,923, filed July 2, 1999, which is a continuation-in-part of prior U.S. Patent application serial no. 09/282,165, filed March 31, 1999, each of which is herein incorporated by reference in its entirety.--

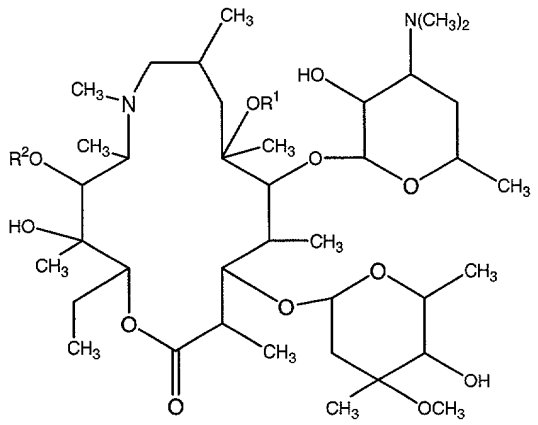
In the Claims:

Please first add claims 45-94 and then cancel claims 1-44 without prejudice.

45. A process for treating an eye, comprising:
topically applying an azalide antibiotic to an eye in an amount effective to treat or prevent infection in a tissue of the eye.

46. The process according to claim 45, wherein said eye is suffering from at least one condition selected from the group consisting of conjunctivitis, ophthalmia neonatorum, trachoma, corneal ulcers, keratitis, keratoconjunctivitis, endophthalmitis, infectious uveitis and combinations thereof, and said amount of said azalide antibiotic is therapeutically effective to treat said condition.

47. The process according to claim 45, wherein said azalide antibiotic comprises a compound of formula (I):



(I)

wherein R^1 and R^2 each independently represent a hydrogen atom or a methyl group.

48. The process according to claim 47, wherein said azalide antibiotic comprises azithromycin.

49. The process according to claim 45, wherein said application provides a therapeutically effective concentration of azalide antibiotic within a tissue of the eye for at least 8 hours.

50. The process according to claim 49, wherein said application provides a therapeutically effective concentration of azalide antibiotic within a tissue of the eye for at least 12 hours.

51. The process according to claim 50, wherein said application provides a

therapeutically effective concentration of azalide antibiotic within a tissue of the eye for at least 18 hours.

52. The process according to claim 45, wherein said topically applying comprises supplying a depot of a composition containing said azalide antibiotic on the eye.

53. The process according to claim 52, wherein said depot is an aqueous polymeric suspension of said azalide antibiotic.

54. The process according to claim 53, wherein said aqueous polymeric suspension further comprises an additional medicament.

55. The process according to claim 54, wherein said additional medicament is selected from the group consisting of amikacin, gentamycin, tobramycin, streptomycin, netilmycin, kanamycin ciprofloxacin, norfloxacin, ofloxacin, trovafloxacin, lomefloxacin, levofloxacin, enoxacin, sulfonamides, polymyxin, chloramphenicol, neomycin, paramomomycin, colistimethate, bacitracin, vancomycin, tetracyclines, rifampins, cycloserine, beta-lactams, cephalosporins, amphotericins, fluconazole, flucytosine, natamycin, miconazole, ketoconazole, corticosteroids, diclofenac, flurbiprofen, ketorolac, suprofen, comolyn, lodoxamide, levocabastin, naphazoling, antazoline, and pheniramimane.

56. The process according to claim 52, wherein said depot is a composition selected from the group consisting of an aqueous suspensions, ointments, and inserts.

57. The process according to claim 56, wherein said composition further comprises an additional medicament.

58. The process according to claim 57, wherein said additional medicament is selected from the group consisting of antibiotics, antivirals, antifungals, anesthetics, anti-inflammatory agents, and anti-allergic agents.

59. The process according to claim 52, wherein said depot remains for at least 30

minutes after administration.

60. The process according to claim 59, wherein said depot remains for at least 4 hours after administration.

61. An aqueous polymeric suspension comprising water, 0.01% to 1.0% of an azalide antibiotic and 0.1 to 10% of a polymeric suspending agent.

62. The suspension according to claim 61, further comprising an additional medicament selected from the group consisting of antibiotics, antivirals, antifungals, anesthetics, anti-inflammatory agents, and anti-allergic agents.

63. The suspension according to claim 62, wherein said additional medicament is contained in an amount of from 0.01 to 5.0%.

64. The suspension according to claim 61, wherein said additional medicament is selected from the group consisting of amikacin, gentamycin, tobramycin, streptomycin, netilmycin, kanamycin ciprofloxacin, norfloxacin, ofloxacin, trovafloxacin, lomefloxacin, levofloxacin, enoxacin, sulfonamides, polymyxin, chloramphenicol, neomycin, paramomomycin, colistimethate, bacitracin, vancomycin, tetracyclines, rifampins, cycloserine, beta-lactams, cephalosporins, amphotericins, fluconazole, flucytosine, natamycin, miconazole, ketoconazole, corticosteroids, diclofenac, flurbiprofen, ketorolac, suprofen, comolyn, lodoxamide, levocabastin, naphazoling, antazoline, and pheniramimane.

65. A topical ophthalmic composition comprising an effective amount of an azalide antibiotic and an ophthalmically acceptable carrier.

66. The composition according to claim 65, wherein said azalide antibiotic comprises azithromycin.

67. The composition according to claim 65, further comprising an additional medicament selected from the group consisting of antibiotics, antivirals, antifungals,

anesthetics, anti-inflammatory agents, and anti-allergic agents.

68. The composition according to claim 67, wherein said composition is fluid; said azalide antibiotic is contained in an amount of from about 0.01 to 2.0%; and said additional medicament is contained in an amount of from about 0.01 to 5.0%.

69. The composition according to claim 68, wherein said ophthalmically acceptable carrier is water or an aqueous solution and said additional medicament is selected from the group consisting of amikacin, gentamycin, tobramycin, streptomycin, netilmycin, kanamycin ciprofloxacin, norfloxacin, ofloxacin, trovafloxacin, lomefloxacin, levofloxacin, enoxacin, sulfonamides, polymyxin, chloramphenicol, neomycin, paramomomycin, colistimethate, bacitracin, vancomycin, tetracyclines, rifampins, cycloserine, beta-lactams, cephalosporins, amphotericins, fluconazole, flucytosine, natamycin, miconazole, ketoconazole, corticosteroids, diclofenac, flurbiprofen, ketorolac, suprofen, comolyn, lodoxamide, levocabastin, naphazoling, antazoline, and pheniramimane.

70. A process for treating an eye, comprising:
topically applying an azalide antibiotic to an eye of a non-human animal in an amount effective to treat or prevent infection in a tissue of the eye.

71. The process according to claim 70, wherein said non-human animal is a mammal.

72. The process according to claim 71, wherein said mammal is selected from the group consisting of cows, sheep, horses, pigs, goats, rabbits, dogs, and cats.

73. The process according to claim 70, wherein said topical application comprises supplying a depot of a composition containing said azalide antibiotic on the eye.

74. The process according to claim 73, wherein said depot is an aqueous polymeric suspension of said azalide antibiotic.

75. The process according to claim 74, wherein said aqueous polymeric suspension further comprises an additional medicament.

76. The process according to claim 75, wherein said additional medicament is selected from the group consisting of amikacin, gentamycin, tobramycin, streptomycin, netilmycin, kanamycin ciprofloxacin, norfloxacin, ofloxacin, trovafloxacin, lomefloxacin, levofloxacin, enoxacin, sulfonamides, polymyxin, chloramphenicol, neomycin, paramomomycin, colistimethate, bacitracin, vancomycin, tetracyclines, rifampins, cycloserine, beta-lactams, cephalosporins, amphotericins, fluconazole, flucytosine, natamycin, miconazole, ketoconazole, corticosteroids, diclofenac, flurbiprofen, ketorolac, suprofen, comolyn, lodoxamide, levocabastin, naphazoling, antazoline, and pheniramimane.

77. The process according to claim 73, wherein said depot is a composition selected from the group consisting of an aqueous suspensions, ointments, and inserts.

78. The process according to claim 77, wherein said depot remains for at least 30 minutes after administration.

79. The process according to claim 78, wherein said depot remains for at least 4 hours after administration.

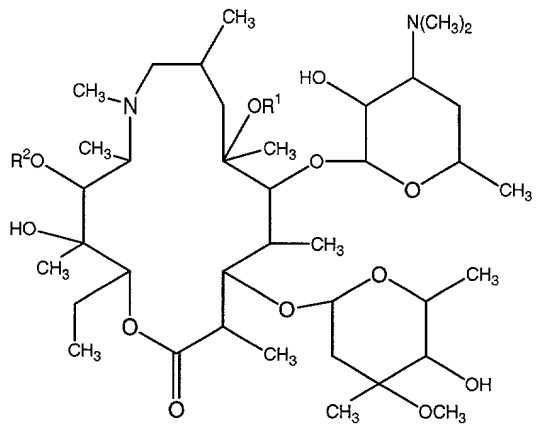
80. The process according to claim 70, wherein said composition further comprises an additional medicament.

81. The process according to claim 80, wherein said additional medicament is selected from the group consisting of antibiotics, antivirals, antifungals, anesthetics, anti-inflammatory agents, and anti-allergic agents.

82. The process according to claim 70, wherein said eye is suffering from at least one condition selected from the group consisting of conjunctivitis, ophthalmia neonatorum, trachoma, corneal ulcers, keratitis, keratoconjunctivitis, endophthalmitis, infectious uveitis and combinations thereof, and said amount of said azalide antibiotic is therapeutically

effective to treat said condition.

83. The process according to claim 70, wherein said azalide antibiotic comprises a compound of formula (I):



(I)

wherein R^1 and R^2 each independently represent a hydrogen atom or a methyl group.

84. The process according to claim 83, wherein said azalide antibiotic comprises azithromycin.

85. The process according to claim 70, wherein said application provides a therapeutically effective concentration of azalide antibiotic within a tissue of the eye for at least 8 hours.

86. The process according to claim 85, wherein said application provides a therapeutically effective concentration of azalide antibiotic within a tissue of the eye for at least 12 hours.

87. The process according to claim 86, wherein said application provides a therapeutically effective concentration of azalide antibiotic within a tissue of the eye for at

least 18 hours.

88. A topical opthalmic composition for use in a non-human animal, comprising an effective amount of an azalide antibiotic and an opthalmically acceptable carrier.

89. The composition according to claim 88, wherein said non-human animal is a mammal.

90. The composition according to claim 89, wherein said mammal is selected from the group consisting of cows, sheep, horses, pigs, goats, rabbits, dogs, and cats.

91. The composition according to claim 88, wherein said azalide antibiotic comprises azithromycin.

92. The composition according to claim 88, further comprising an additional medicament selected from the group consisting of antibiotics, antivirals, antifungals, anesthetics, anti-inflammatory agents, and anti-allergic agents.

93. The composition according to claim 92, wherein said composition is fluid; said azalide antibiotic is contained in an amount of from about 0.01 to 2.0%; and said additional medicament is contained in an amount of from about 0.01 to 5.0%.

94. The composition according to claim 88 further comprising an additional medicament, wherein said ophthalmically acceptable carrier is water or an aqueous solution and said additional medicament is selected from the group consisting of amikacin, gentamycin, tobramycin, streptomycin, netilmycin, kanamycin ciprofloxacin, norfloxacin, ofloxacin, trovafloxacin, lomefloxacin, levofloxacin, enoxacin, sulfonamides, polymyxin, chloramphenicol, neomycin, paramomomycin, colistimethate, bacitracin, vancomycin, tetracyclines, rifampins, cycloserine, beta-lactams, cephalosporins, amphotericins, fluconazole, flucytosine, natamycin, miconazole, ketoconazole, corticosteroids, diclofenac, flurbiprofen, ketorolac, suprofen, comolyn, lodoxamide, levocabastin, naphazoling,

antazoline, and pheniramimane.

Remarks

Claims 1-44 have been cancelled without prejudice to or disclaimer of the subject matter therein. New claims 45-94 are added. These changes introduce no new matter, and their entry is respectfully requested. Upon entry of the foregoing amendment, claims 45-94 are pending in the application, of which claims 45, 61, 65, 70, and 88 are independent claims.

Conclusion

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

Andrew S. Brenc (Reg. No. 45,534)

Date: 1-24-01

HOWREY SIMON ARNOLD & WHITE, LLP
Box No. 34
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2402
(202) 783-0800